PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR §807.92)

510k number: K100163

Applicant:
Vygon
103A Park Dr
Montgomeryville, PA 18936

Contact Name:
Cindy Varughese
Sr. Manager, Regulatory Affairs
Phone: 800-473-5414
Fax: 215-672-6740

Trade Name: Nutrisafe 2 Feeding Tube
Common Name: Tubes, Feeding
Regulation Number: 876.5980
Product Code: FPD
Classification Name: Gastrointestinal tube and accessories devices, 21 CFR §876.5980
Regulatory Class: Class II
Predicate Device: Nutrisafe 2 Feeding Tubes, K060944
Date Prepared: March 15, 2011

Device Description:
The Nutrisafe 2 feeding tubes are a product line extension to the existing Nutrisafe 2 feeding tubes. The subject feeding tubes are available in several sizes and in two materials. The feeding system contains a unique connection that does not incorporate a luer, reducing the risk of inadvertently connecting to intravenous connectors. The locking connection reduces the risk of involuntary disconnection; voluntary disconnection is achieved by simply unscrewing the hub connections.

Intended Use:
For nasogastric/oralgastric enteral feeding, incorporating safety connectors which reduce the risk of misconnections between feeding tubes and intravenous connectors.

Technology Characteristics:
The subject Nutrisafe 2 feeding tubes have the same technological characteristics of the predicate device with the exception of the size of the tubes. The subject devices are 14, 16, and 18F, while the predicate devices range from 4F-12F. The technological characteristics are substantially equivalent to the predicate device.

Non-Clinical Summary:
Non-clinical verification of Nutrisafe 2 Feeding Tubes was conducted through in-vitro bench testing. Results of this testing indicate that the Nutrisafe 2 Feeding Tube product line extension meets all specifications and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Cindy Varughese
Sr. Regulatory Affairs Manager
Vygon
103A Park Drive
MONTGOMERYVILLE PA 18936

OCT 13 2011

Re: K100163
Trade/Device Name: Nutrisafe 2 Feeding Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: FPD
Dated: September 20, 2011
Received: September 21, 2011

Dear Ms. Varughese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K100163**

Device Name: **Nutrisafe 2 Feeding Tube**

Indications For Use: **For nasogastric/oralgastric enteral feeding, incorporating safety connectors which reduce the risk of misconnections between feeding tubes and intravenous connectors.**

Prescription Use __X__ AND/OR Over-The-Counter Use
_____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K100163